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Attorney Docket No. 7500-0004.10
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:
JOHN M. PEZZUTO et al.

Serial No.: Divisional of 09/430,337 — Group Art Unit: 1614

Filing Date: October 29, 1999 — Examiner: Kwon, B.

Title: PHARMACEUTICAL FORMULATIONS OF RESVERATROL (as amended herein)

PRELIMINARY AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

This is a preliminary amendment to the patent application identified above. Prior to examination of the subject application, please enter the following amendments to the specification and claims.

AMENDMENTS

IN THE TITLE:

Please amend the title on page 1, lines 1 and 2, and page 42, lines 5 and 6, as indicated in Appendix A. The amended title reads as follows:

PHARMACEUTICAL FORMULATIONS OF RESVERATROL

IN THE SPECIFICATION:

Please amend the paragraph on page 1, at lines 12-14 (under the heading "CROSS REFERENCE TO RELATED APPLICATIONS") as indicated in Appendix A. The amended paragraph reads as follows:

--This application is a divisional of U.S. Patent Application Serial No. 09/430,337, filed October 29, 1999, which is a continuation-in-part of U.S. Patent Application Serial No. 09/005,114, filed January 9, 1998, the disclosure of which are incorporated by reference in their entireties. --

IN THE CLAIMS:

Please cancel claims 1-67.

Please add new claims 68-91 as indicated in Appendix A. The new claims are reproduced below.

68. (New) A topical pharmaceutical formulation for use in preventing or treating skin conditions, disorders and diseases associated with inflammation, comprising a topical carrier and a therapeutically effective concentration of an active agent consisting essentially of resveratrol or a pharmacologically acceptable salt, ester, amide, prodrug or analogs thereof, and combinations of any of the foregoing, wherein the therapeutically effective amount is approximately 1.0 wt.% to 30 wt.% of the formulation.

69. (New) The formulation of claim 68, wherein the active agent is *cis*-resveratrol or a pharmacologically acceptable salt, ester, amide, prodrug or analog thereof.

70. (New) The formulation of claim 69, wherein the active agent is *cis*-resveratrol.

71. (New) The formulation of claim 69, wherein the active agent is a conjugate of *cis*-resveratrol and a mono- or di-saccharide.

72. (New) The formulation of claim 71, wherein the active agent is *cis*-resveratrol glucoside.

73. (New) The formulation of claim 68, wherein the active agent is *trans*-resveratrol or a pharmacologically acceptable salt, ester, amide, prodrug or analog thereof.

74. (New) The formulation of claim 73, wherein the active agent is *trans*-resveratrol.

75. (New) The formulation of claim 74, wherein the active agent is a conjugate of *trans*-resveratrol and a mono- or di-saccharide.

76. (New) The formulation of claim 75, wherein the active agent is *trans*-resveratrol glucoside.

77. (New) The formulation of claim 68, wherein the active agent comprises a mixture of *cis*-resveratrol and *trans*-resveratrol.

78. (New) The formulation of claim 68, wherein the topical carrier comprises an ointment base and the formulation is an ointment.

79. (New) The formulation of claim 68, wherein the topical carrier comprises a cream base and the formulation is a cream.

80. (New) The formulation of claim 68, wherein the topical carrier comprises a lotion base and the formulation is a lotion.

81. (New) The formulation of claim 68, wherein the formulation is a gel and additionally includes a gelling agent.

82. (New) The formulation of claim 68, wherein the topical carrier comprises an aqueous liquid and the formulation is a solution.

83. (New) The formulation of claim 68, wherein the formulation is an isotropically clear dispersion.

84. (New) The formulation of claim 68, comprising approximately 0.25 wt.% to 75 wt.% active agent.

85. (New) The formulation of claim 84, comprising approximately 0.25 wt.% to 30 wt.% active agent.

86. (New) The formulation of claim 85, comprising approximately 0.5 wt.% to 15 wt.% active agent.

87. (New) The formulation of claim 86, comprising approximately 1.0 wt.% to 10 wt.% active agent.

88. (New) A topical pharmaceutical formulation comprising:

approximately 1.0 wt.% to 30 wt.% of an active agent consisting essentially of resveratrol or a pharmacologically acceptable salt, ester, amide, prodrug or analog thereof, or a combination of any of the foregoing;

approximately 2 wt.% to 20 wt.% emulsifiers;

approximately 2 wt.% to 20 wt.% emollient;

approximately 2 wt.% to 50 wt.% solubilizer;

approximately 0.1 wt.% to 0.2 wt.% preservative; and

water.

89. (New) The formulation of claim 88, wherein the emulsifiers are selected from the group consisting of glyceryl monostearate, polyoxyethylene stearate, polyethylene glycol,

ethylene glycol palmitostearate, caprilic/capric triglycerides, oleoyl macrogolglycerides, and combinations thereof.

90. (New) The formulation of claim 88, wherein the emollient is selected from the group consisting of propylene glycol, glycerol, isopropyl myristate, PPG-2 ether propionate, and combinations thereof.

91. (New) The formulation of claim 88, wherein the solubilizer is selected from the group consisting of diethylene glycol monoethyl ether, diethylene glycol monomethyl ether, diethylene glycol monoethyl ether oleate, polyethylene glycol, polyethylene castor oil derivatives, PEG-8 caprylic/capric glycerides, alkyl methyl sulfoxides, pyrrolidones and dimethyl acetamide.

REMARKS

With the above amendment to the specification, reference has been added to this application's status as a divisional application of Serial No. 09/137,728.

Claims 1-67 have been cancelled.

New claims 68-91 have been added. The new claims are substantially identical to claims 42-67 as originally filed in the parent application but have been renumbered to reflect the accidental omission of claims 54 and 55 and amended to specify that the active agent consists essentially of resveratrol or a pharmacologically acceptable salt, ester, amide, prodrug or analog thereof, or a combination of any of the foregoing, and is present in an amount of approximately 1.0 wt.% to 30 wt.% of the formulation. Support for these amendments is found on page 17, lines 16 to 21, of the specification. Accordingly, no new matter has been added.

As the newly added formulation claims substantially correspond to the claims that have been allowed and will issue in the parent application, this application is in condition for allowance and a prompt notification to that effect would be much appreciated.

The Examiner is welcome to contact the undersigned attorney at (650) 330-0900, if there are any questions concerning this communication.

Respectfully submitted,

2/7/02
Date

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APPENDIX A- AMENDMENTS

REDACTED SPECIFICATION INDICATING AMENDMENTS MADE AND NEW CLAIMS

IN THE TITLE:

Please amend the title on page 1, lines 1 and 2, and page 42, lines 5 and 6, as indicated below. Text to be deleted is indicated as ~~deleted text~~, while added subject matter is underlined.

PHARMACEUTICAL FORMULATIONS OF RESVERATROL ~~AND METHODS OF USE THEREOF~~

IN THE SPECIFICATION:

Please amend the paragraph beginning on line 12 of page 1 under the heading "Cross-Reference to Related Applications" as indicated below. Text to be deleted is indicated as ~~deleted text~~, while added subject matter is underlined.

This application is a divisional of U.S. Patent Application Serial No. 09/430,337, filed October 29, 1999, which is a continuation-in-part of U.S. Patent Application Serial No. 09/005,114, filed January 9, 1998, the ~~disclosure~~ disclosures of which ~~is~~ are incorporated by reference in ~~its entirety~~ their entireties.

IN THE CLAIMS:

Please add new claims 68-91 as follows:

68. (New) A topical pharmaceutical formulation for use in preventing or treating skin conditions, disorders and diseases associated with inflammation, comprising a topical carrier and a therapeutically effective concentration of an active agent consisting essentially of resveratrol or a pharmacologically acceptable salt, ester, amide, prodrug or analogs thereof, and combinations of any of the foregoing, wherein the therapeutically effective amount is approximately 1.0 wt.% to 30 wt.% of the formulation.

69. (New) The formulation of claim 68, wherein the active agent is *cis*-resveratrol or a pharmacologically acceptable salt, ester, amide, prodrug or analog thereof.

70. (New) The formulation of claim 69, wherein the active agent is *cis*-resveratrol.

71. (New) The formulation of claim 69, wherein the active agent is a conjugate of *cis*-resveratrol and a mono- or di-saccharide.

72. (New) The formulation of claim 71, wherein the active agent is *cis*-resveratrol glucoside.

73. (New) The formulation of claim 68, wherein the active agent is *trans*-resveratrol or a pharmacologically acceptable salt, ester, amide, prodrug or analog thereof.

74. (New) The formulation of claim 73, wherein the active agent is *trans*-resveratrol.

75. (New) The formulation of claim 74, wherein the active agent is a conjugate of *trans*-resveratrol and a mono- or di-saccharide.

76. (New) The formulation of claim 75, wherein the active agent is *trans*-resveratrol glucoside.

77. (New) The formulation of claim 68, wherein the active agent comprises a mixture of *cis*-resveratrol and *trans*-resveratrol.

78. (New) The formulation of claim 68, wherein the topical carrier comprises an ointment base and the formulation is an ointment.

79. (New) The formulation of claim 68, wherein the topical carrier comprises a cream base and the formulation is a cream.

80. (New) The formulation of claim 68, wherein the topical carrier comprises a lotion base and the formulation is a lotion.

81. (New) The formulation of claim 68, wherein the formulation is a gel and additionally includes a gelling agent.

82. (New) The formulation of claim 68, wherein the topical carrier comprises an aqueous liquid and the formulation is a solution.

83. (New) The formulation of claim 68, wherein the formulation is an isotropically clear dispersion.

84. (New) The formulation of claim 68, comprising approximately 0.25 wt.% to 75 wt.% active agent.

85. (New) The formulation of claim 84, comprising approximately 0.25 wt.% to 30 wt.% active agent.

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approximately 2 wt.% to 20 wt.% emulsifiers;

approximately 2 wt.% to 20 wt.% emollient;

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water.